NO. 19-60394

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Impax Laboratories, Incorporated, a corporation,

Petitioner,

v.

Federal Trade Commission,

Respondent.

On Petition for Review From
The Federal Trade Commission, No. 9373
Entered March 28, 2019

BRIEF OF THE STATES OF MISSISSIPPI, WASHINGTON, ALASKA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, HAWAII, IDAHO, ILLINOIS, IOWA, MAINE, MARYLAND, MASSACHUSETTS, MINNESOTA, MONTANA, NEBRASKA, NEW MEXICO, NORTH CAROLINA, OREGON, PENNSYLVANIA, VIRGINIA, AND WISCONSIN AS *AMICUS CURIAE* IN SUPPORT OF THE RESPONDENT

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TABLE OF CONTENTS

Cases

Other Authorities

I. STATEMENT OF INTEREST

This appeal by Impax Laboratories, Inc. ("Impax") ignores fundamental rule of reason principles and their application to anticompetitive "pay-for-delay" agreements. Purporting to settle drug patent disputes, these "pay-for-delay" or "reverse payment" agreements involve large unjustified payments or transfers of value from a brand drug company to its generic rival in exchange for its rival's agreement to delay selling a competitive drug.

The *Amici* States of Mississippi, Washington, Alaska, California, Colorado, Connecticut, Delaware, District of Columbia, Hawaii, Idaho, Illinois, Iowa, Maine, Maryland, Massachusetts, Minnesota, Montana, Nebraska, New Mexico, North Carolina, Oregon, Pennsylvania, Virginia, and Wisconsin ("States") as pharmaceutical purchasers and reimbursers, and as enforcers of both federal and state antitrust laws, have a strong interest in vigorous competition in pharmaceutical markets. Prescription drugs represent a major expenditure for the States. States purchase drugs and make reimbursements for the cost of drugs through state Medicaid and other public health programs. In 2018, state entities across the country spent approximately $12 billion through

Medicaid alone on prescription drugs.[1] Prescription drugs in the U.S. cost consumers more than $335 billion annually.[2] State and local governments typically reimburse or otherwise pay for some 17% of the total drug purchases, or about $56.95 billion annually.[3] As major drug purchasers, the States have a strong interest in avoiding the increased costs caused by drug companies, compensating their generic rivals to not compete. As these "pay-for-delay" agreements cost drug purchasers at least $3.5 billion per year in increased drug prices,[4] the States and their citizens suffer direct and substantial economic harm in the form of increased drug prices and reduced consumer choices.

The States' attorneys general are the chief law enforcement officers of their respective states and are charged with the enforcement of federal and state antitrust laws. The States have a long history of prosecuting cases involving "pay-for-delay" agreements,[5] including the underlying action in which the

[1] U.S. DEP'T OF HEALTH & HUM. SVCS., NATIONAL HEALTH EXPENDITURES BY TYPE OF SERVICE AND SOURCE OF FUNDS: CALENDAR YEAR 1960-2018, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NationalHealthAccountsHistorical

[2] *Id*.

[3] U.S. DEP'T OF HEALTH & HUM. SVCS., NATIONAL HEALTH EXPENDITURES 2017 HIGHLIGHTS, available at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/highlights.pdf

[4] FED. TRADE COMM'N, PAY-FOR-DELAY: HOW DRUG COMPANY PAY-OFFS COST CONSUMERS BILLIONS: A FEDERAL TRADE COMMISSION STAFF STUDY, 10 (Jan. 2010) available at: https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf ($3.5 billion per year in savings to consumers if "pay-for-delay" were eliminated, but possibly as high as $7.5 billion.).

[5] *See e.g., California v. Teva Pharm. Indus., Ltd.*, No. 2:19-CV-03281, 2019 WL 3974977 (E.D. Pa. filed July 29, 2019); *State v. Teva Pharm. Indus., Ltd.*, 242 So. 3d 597 (La. Ct. App. 2018); *New York v. Cephalon, Inc.*, No.2:16-CV-04234 (E.D. Pa. July 25, 2017); *State v. Allergan Plc*, No. 4:17-CV-00562 (N.D.

United States Supreme Court issued the landmark decision, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013) ("*Actavis*").[6] Thus, while the States do not take a position on the merits of this particular case, the States have a substantial interest in ensuring that the application of federal antitrust laws is consistent with controlling legal precedent and sound public policy.[7]

For the sake of pharmaceutical antitrust enforcement throughout the United States and particularly for future cases, which may be filed within the Fifth Circuit, it is vitally important that this Court issue a ruling consistent with *Actavis* and not narrow the rule of law as advocated by Impax.

Cal. filed Feb. 3, 2017); *Colorado v. Warner Chilcott Holdings Co. III*, No. 05-CV- 2182 (CKK), 2007 WL 6215857 (D.D.C. Mar. 24, 2007); *In re Terazosin Hydrochloride Antitrust Litig*., 352 F. Supp. 2d 1279 (S.D. Fla. 2005); *In re Cardizem CD Antitrust Litig.*, 332 F.3d 896 (6th Cir. 2003).

[6] This action was originally titled *FTC and the State v. Watson Pharm., Inc*. filed on January 27, 2009 in Central District of California under case number CV-09-00598 AHM PLAx. *FTC v. Watson Pharm., Inc.* 611 F. Supp 2d 1081 (C.D. Cal. 2009). After it was transferred to Georgia, over the jurisdictional objections of the State of California, California entered a voluntary dismissal. Moreover, the States have authored numerous *amicus curiae* briefs challenging these agreements, filed in the United States and California Supreme Courts as well as in several Courts of Appeals.

[7] *Amici curiae* briefs filed by the states on "pay-for-delay" issues include but are not limited to the *Amicus* Brief of the California Attorney General, *In re Cipro Cases I & II*, 348 P. 3d 845 (2015) (No. S198616) 2014 WL 1765268; Brief for the States of Mississippi et.al., *In re Lamictal Direct Purchaser Litig.*, 18 F.Supp.3d 560 (D.N.J. 2014) 2014 WL 282755; Brief for the States of New York et. al. as *Amici Curiae* Supporting Petitioner, *FTC v. Watson Pharm.* 568 U.S. 1066 (No. 12-416) 2013 WL 391000; Brief of the States of California et. al. as *Amici Curiae* Supporting Petitioners, *La. Wholesale Drug Co. v. Bayer AG*, 562 U.S. 1280 (2011) (No. 10-762) 2011 WL 96299; Brief of the States of California et. al. as *Amici* Curiae, *Ark. Carpenters Health and Welfare Fund v. Bayer AG.*, 604 F.3d 98 (2d Cir. 2010); Brief of the States of California et. al. as *Amici* Curiae, *In re Ciprofloxacin Hydrochloride Antitrust Litig*., 544 F.3d 1323 (Fed. Cir. 2008) (No. 05-2851) 2008 WL 576744.

II. SUMMARY OF ARGUMENT

The Federal Trade Commission ("FTC") found that "[t]he reverse payment here consisted of the No-AG Commitment and the 'Endo Credit,' a payment Endo would make in the event the Opana ER market declined in the two and a half years between the time of settlement and Impax's entry date." *In re Impax Labs., Inc*., No. 9373, 2019-1 Trade Cases P 80723, 2019 WL 1552939 *6 (F.T.C. Mar. 28, 2019) ("FTC Opinion"). The FTC properly determined that a restraint of trade can only be justified by or balanced against procompetitive benefits or objectives that have a logical nexus to the restraint itself. The ruling in the FTC Opinion is grounded on bedrock antitrust jurisprudence that requires any purported procompetitive benefit, raised to offset any challenged restraint, to be logically related to and attained uniquely by the challenged restraint. AREEDA & HOVENKAMP, ANTITRUST LAW, ¶1505b, at 417-419 (3d and 4th eds. 2010-2017); *Nat'l Soc. of Prof'l Eng'rs v. United States*, 435 U.S. 679, 688–90 (1978). Without this essential and logical nexus between the restraint and the procompetitive benefit, unlawful restraints are not "justified." Otherwise, these costly anticompetitive agreements would always escape condemnation by the mere proffer of unrelated benefits.

III. ARGUMENT

A. Procompetitive benefits must be directly related to the challenged restraint of trade in order to be used as a justification.

Actavis allows defendants to prove (as in other rule of reason cases) that the anticompetitive consequences of a "reverse payment" agreement are justified by procompetitive benefits. *Actavis*, 570 U.S. at 156. *Actavis*, and the FTC Opinion relying on *Actavis*, follow well-established rule of reason analysis that once a restraint is shown to have anticompetitive harm, the burden shifts to the "defendant to show a procompetitive rationale for the restraint." *Ohio v. Am. Express Co.*, 138 S.Ct. 2274, 2284 (2018) ("*Amex*"). It is also black letter law that antitrust defendants must provide *prima facie* evidence that the restraints directly led to the benefits the defendant seeks to claim. *See e.g.*, *Broad Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1, 20 (1979) (procompetitive effects on the marketplace must be actually attributable to the alleged restraint); *In re Polygram Holding, Inc.*, 136 F.T.C. 310, 347, *enforced*, *Polygram Holding, Inc. v. FTC*, 416 F.3d 29 (D.C. Cir. 2005) (to establish a procompetitive justification for its anticompetitive conduct, a defendant must "articulate the specific link between the challenged restraint and the purported justification."). The FTC, therefore, properly placed the burden on Impax to "adduce facts tying any cognizable procompetitive benefits to the elimination of this risk" and required

it to prove "any link between the actual restraint and the benefits." FTC Opinion at *31. Yet, Impax denies it needs to show any link.

Not only is the FTC's requirement of a logical nexus between the restraint and the procompetitive rationale grounded on long and well-established antitrust precedent[8], it also rests on sound public policy underlying the rule of reason analysis. While the first step in the rule of reason analysis establishes the anticompetitive impact of the challenged conduct, subsequent steps of the analysis explore offsetting or justifying excuses for this anticompetitive conduct to determine whether the conduct can be considered lawful or unlawful. FTC Opinion at *15; *Amex,* 138 S.Ct. at 2284.

Herbert Hovenkamp explains the critical role that this nexus requirement serves in antitrust analysis: "[I]f the defendants have a procompetitive

[8] S*ee, e.g., Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of the Univ. of Okla.*, 468 U.S. 85, 117-19 (1984). *See also N. Tex. Specialty Physicians v. FTC*, 528 F.3d 346, 368-69 (5th Cir. 2008) (defendant must show that the restraint bears a "logical nexus to [the] claimed efficiencies,' meaning that the efficiencies either "result from or are in any way connected to" the restraint); *Realcomp II, Ltd. v. FTC*, 635 F.3d 815, 835 (6th Cir. 2011) (affirming FTC's findings that the respondent had not "demonstrated a connection" between the restraint and the proffered rationale); *United States v. Visa U.S.A., Inc.*, 344 F.3d 229, 238, 243 (2d Cir. 2003) (explaining that defendants "must provide a procompetitive justification for the challenged restraint," and sustaining district court's findings that "no evidence' showed that the restraint advanced the proffered justifications); *In re Polygram,* 136 F.T.C. at 347 (requiring defendant to "articulate the specific link between the challenged restraint and the purported justifications"); *In re Cipro Cases I & II*, 348 P.3d 845,871 (Cal. 2015) (concluding that a plaintiff will prevail if it "eliminate[s] the possibility that litigation costs or other products or services could explain the consideration" and "dispel[s] each additional justification the defendants put forward to explain the consideration").

justification, it must have been a motivating factor for the restraint, and the defendants should be able to establish it rather easily." HERBERT HOVENKAMP, *The Rule of Reason*, 70 FLA. L. REV. 81, 107 (2018). He further explains that defendants have "the burden of coming forward with allegations and evidence that the justifications claimed are legitimate in principle and are *actually promoted significantly by the restraint*." AREEDA & HOVENKAMP, supra, ¶1511c, at 466 (emphasis added). Under the rule of reason, "[a]n allegedly legitimate objective is, of course, entirely immaterial unless it is served *by the challenged restraint.*" *Id*. ¶1505a, at 415 (emphasis added). Thus, the procompetitive rationales are often determinative of the ultimate lawfulness of the anticompetitive conduct.

Recently, the Ninth Circuit explained that, when the challenged restraint in question bears "no relation" to the procompetitive aims of the organization's general plan, or when the "legitimate procompetitive purposes" at issue may be accomplished through a "substantially less restrictive means," this falsifies the proposition that the restraint of trade is necessary for the alleged procompetitive benefit. *O'Bannon v. Nat'l Collegiate Athletic Ass'n*, 802 F.3d 1049, 1075 (9th Cir. 2015); *United States v. Grinnell Corp*., 384 U.S. 563, 570–71 (1966) (If the challenged restraint has only pretextual use in facilitating the mentioned

procompetitive outcome, the challenged restraint is likely to be the "willful acquisition or maintenance" of monopoly power which the Supreme Court has continuously condemned).

As scholars elucidate and these cases demonstrate, without a plausible logical nexus between the challenged restraint and its alleged procompetitive benefits, those procompetitive benefits cannot justify, offset or balance a restraint of trade and are thus merely a pretext for the restraint of trade. *See e.g.*, *McWane, Inc. v. FTC*, 783 F.3d 814, 841-42 (11th Cir. 2015) ("Such justifications, however, cannot be 'merely pretextual.'"). Under those circumstances, one cannot move to the next step of the analysis and evaluate whether the restraint is "reasonably necessary" to achieve the benefit.

B. The Supreme Court has consistently focused on the justification for the specific restrictive provision.

Throughout antitrust jurisprudence, the Supreme Court has consistently considered justifications for the restrictive provision in question, rather than justifications related to other provisions of the whole agreement or document. See, e.g., *Bd. Of Trade of Chi. v. United States*, 246 U.S. 231, 238, 240 (1918) (Court solely analyzed the procompetitive and anticompetitive impact of "the call" rule of the Chicago Board of Trade rather than analyzing the Board's entire system of trading rules); *Nat'l Soc. of Prof'l Eng'rs,* 435 U.S. at 682-683 (Court

analyzed the procompetitive justifications and anticompetitive effects solely of engineer trade association rule that prohibited competitive bidding among engineers, not the comprehensive code of engineering ethics in which it was found); *Nat'l Collegiate Athletic Assn*, 468 U.S. at 91-94, 117-18 (Court focused on procompetitive justification of NCAA rule, imposing caps on number of games that could be televised, which was imbedded in a larger comprehensive set of rules); *FTC v. Indep. Fed'n of Dentists*, 476 U.S. 447, 454, 462 (1986) (Court analyzed justification for a dentist association's policy to not submit x-rays to dental insurers for use in benefits determinations though this policy existed within the Federation's broad "legal, moral, and ethical policy of quality dental care.").

Recently, the Supreme Court narrowly focused on the justifications for "Amex's antisteering provisions" without evaluating other provisions in American Express's lengthy merchant contracts. *Amex,* 138 S. Ct. at 2288. The Supreme Court has been unequivocal: any procompetitive rationales for the challenged restraint in Impax's "pay-for-delay" agreement must be evaluated according to the procompetitive rationale for the challenged restraint and not the entire agreement in which the restraint may be included.

Impax's reliance on the cases cited in its brief is misguided. Impax improperly relies on language from *In re Wellbutrin XL Antitrust Litig*., 133 F. Supp. 3d 734, 753 (E.D. Pa. 2015) *aff'd*, 868 F.3d 132 (3d Cir. 2017) ("*Wellbutrin XL*"), claiming it authorizes a departure from *Actavis* and an evaluation of the justifications of the settlement as a whole. However, the *Wellbutrin XL* court looked at the totality of the settlement agreements because the agreements did not resolve the patent litigation, and it needed to evaluate whether they were within the scope of *Actavis* at all.[9] On appeal, the Third Circuit found a lack of standing and did not perform a rule of reason analysis. *In re Wellbutrin XL Antitrust Litig*., 868 F.3d 132, 165 (3d. Cir. 2017).

Additionally, the District Court's analysis in *Wellbutrin XL* is inconsistent with the Third Circuit's later decision in *In re Lipitor Antitrust Litig.*, 868 F.3d 231, 256-57 (3d Cir. 2017) ("*Lipitor*"), a "pay-for-delay" case like this one. As part of a patent settlement agreement, the parties included a Canadian supply arrangement for generic Lipitor between the parties and resolved other litigation. However, the Third Circuit refused to treat these as relevant procompetitive benefits of the restraint because defendants must "explain[] the presence of the

[9] *See* Michael A. Carrier, *The Curious Case of Wellbutrin: How the Third Circuit Mistook Itself for the Supreme Court,* 103 CORNELL L. REV. 137, 137-38 (2018) (criticizing the *Wellbutrin* court for eschewing numerous aspects of the *Actavis* decision, such as "downplay[ing] the connection between payment and patent weaknesses and resuscitat[ing] the defense based on the risk that the Supreme Court had rejected").

challenged term and show[] the lawfulness *of that term* under the rule of reason." *Id*. at 256-257 (emphases added).

Defendants fare no better relying on *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152 (S.D.N.Y. 2018). There, the court simply noted that whether the settlement agreements were anticompetitive or procompetitive depended "on several complex factual questions that cannot be decided on summary judgment." *Id.* at 198. *Namenda* also undermines Impax's misapplied analysis of *Actavis*, as the court also analyzed the procompetitive benefits and anticompetitive harms of the "Lexapro Amendment" separate and apart from the related settlement agreements. *Id*.

Finally, Impax's reliance on *In re Nexium* is misplaced. *In re Nexium (Esomeprazole) Antitrust Litig.*, 309 F.R.D. 107 (D. Mass. 2015), as amended (Aug. 7, 2015), *aff'd,* 842 F.3d 34 (1st Cir. 2016). In *Nexium*, while the jury found the settlement agreement was anticompetitive, they found that the agreement caused no harm because the generic manufacturer was otherwise not able to enter the market. *Id*. at 145. Therefore, the jury did not even consider and never reached procompetitive justifications.

C. There is no logical factual nexus between the Impax broad patent license and the restraint at issue.

Impax argues that the broad patent license, which it obtained as part of the

overall settlement agreement, should exonerate the paid commitment to defer launching Impax's generic version. However, the patent license for current and future patents is not logically connected to Impax's commitment to defer its launch. Impax's attempt to treat them as connected, without supporting evidence, effectively overrules the core teachings of *Actavis*, and the rule of reason jurisprudence. Impax's failure to identify a logical nexus between the broad license and the challenged unlawful payments is particularly fatal to their arguments in this case.

Additionally, as the FTC has shown, these broad patent licenses are standard fixtures in settlement agreements, suggesting that Hatch-Waxman settlements need not include the types of unlawful payments used in this settlement. Tasked to review all pharmaceutical patent settlements, the FTC found 93% of the settlements granted licenses to patents in addition to those asserted in litigation, and 82% guaranteed that the brand manufacturer would not sue on any patent, even patents it had yet to acquire.[10] Despite the ubiquity of

[10]AGREEMENTS FILED WITH THE FEDERAL TRADE COMMISSION UNDER THE MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003, OVERVIEW OF AGREEMENTS FILED IN FY 2016: A REPORT BY THE BUREAU OF COMPETITION, 1-3, available at: https://www.ftc.gov/reports/agreements-filed-federal-trade-commission-under-medicare-prescription-drug-improvement-fy2016 (Out of 232 settlement agreements, 215 involved the generic manufacturer receiving rights to patents that were not the subject of any litigation between the brand manufacturer and that generic manufacturer; out of these 232 settlements agreements, 191 involved the generic manufacturer receiving licenses or covenants not to sue covering all patents).

these broad license provisions, the FTC also concluded that over 90% of these settlements did not contain "explicit compensation" from the brand to the generic.[11] Thus, these FTC reports establish that parties are able to and do secure broad patent licenses without making the types of unlawful, anticompetitive payments that were found in the Endo-Impax agreement, which incentivized Impax to defer launching their generic version.

The parties' negotiations leading up to the "pay-for-delay" agreement here further contradict Impax's argument that the broad patent license is logically or factually connected to Endo's reverse payment. The parties reached a preliminary agreement on the period of delay, the anticompetitive "no-AG" clause and Endo's credit, with Impax freely admitting, "Endo proposed" and "Endo expressed comfort" with the 2013 market entry dates regardless of any other settlement terms. Impax Brief, p. 7-8. It was only several weeks later that the parties agreed on the broad patent license. *Id*. In effect, Impax's argument, if successful, would undermine the rule of reason analysis required by the Supreme Court's ruling in *Actavis* for "pay-for-delay" agreements and wrongfully inflate

[11] *Id*. (Out of 232 settlement agreements, 14 involved possible compensation in excess of litigation fees and one involved a clear no-AG agreement, meaning 217/232 reported settlements did not have either of the forms of valuable consideration at issue in the underlying litigation resulting in the FTC Opinion). Having not reviewed these agreements, the States takes no position on their legality (under *Actavis* or under the rule of reason generally), or the legality of patent licenses generally in Hatch-Waxman settlements.

drug company profits at the expense of our consumers. This court should not countenance Impax's misguided arguments.

IV. CONCLUSION

For the foregoing reasons, the States respectfully urge this Court to uphold the Federal Trade Commission's decision.

RESPECTFULLY SUBMITTED this 16th day of December, 2019.

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I certify that the foregoing brief complies with the volume limitations of Fed. R. App. P. 32(a)(7)(B) because it contains 3283 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii), and that it complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it was prepared using Microsoft Word 2010 in 14 point Times New Roman type.

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Dated: December 16, 2019 By: s/ Crystal Utley Secoy
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